REMARKS

Applicants respectfully request reconsideration and reexamination of the present application in light of the amendments and the remarks below.

Claims 1 and 2 are pending in this application. Claims 1 and 2 have been amended. These claim amendments are made to clarify the subject matter therein. Therefore, these amendments are submitted in order to place the claims in condition for allowance, and do not disclaim any subject matter to which the Applicants are entitled.

Specification

The Examiner stated that the disclosure is objected to because the disclosure does not contain a separate "Brief Description of the Drawings" section (Paper No. 32104, page 2).

The specification has been amended to include a "Description of the Drawings" section. Support for the description of the drawing may be found on pages 15 and 16 of the specification.

Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1 and 2 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention (Paper No. 32104, page 2). Applicants respectfully traverse this rejection.

Claims 1 and 2 have been amended to recite "organ-specific, tissue-specific, or cell-specific" targeting properties. Support for the amended claims may be found, for example, on page 1, line 7 and page 4, lines 8-11 of the specification. As amended, the claims describe the targeting properties of a recombinant parapoxvirus.

It is thus submitted that the claims 1 and 2 meet the requirements of 35 USC § 112, second paragraph, and reconsideration and withdrawal of the present rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1 and 2 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (Paper No. 32104, pages 3-5).

Claims 1 and 2 has been amended to recite "organ-specific, tissue-specific, or cell-specific" targeting properties.

The Examiner states that there is no evidence that the recombinant virus expressing gD is redirected, i.e. targeted, to any specific cell, tissue or organ (Paper No. 32104, page 3).

In fact, the Example clearly shows that the recombinant virus, gDPPVO (gD-recombinant parapoxvirus ovis), is targeted to cells expressing the herpes virus entry mediator (HVEM), that is, MDBK cells (pages 15-16 of the specification). Specifically, Figure 1 demonstrates that the penetration rate of gDPPVO into MDBK cells is significantly increased as compared to wild-type parapoxvirus ovis (wt PPVO). The increased rate of penetration of the parapoxvirus ovis indicates targeting of the virus towards the MDBK cells. Furthermore, based on the results disclosed in the Example, the heterologous protein is expressed on the surface of the virus particle, and thus leads to the effect of increased penetration rate.

The Examiner also stated that there is no evidence presented in the disclosure that would indicate that any disease would be ameliorated or cured upon administration of the recombinant virus (Paper No. 32104, page 4).

The therapeutic properties of wild-type parapoxvirus ovis are well known in the art (*see, e.g.*, DE 3504940). The present invention provides a means of improving the therapeutic utility of the parapoxvirus ovis such that the generalized paraspecific immunogenicity of the parapoxvirus may be directed in a targeted manner towards the diseased organ, tissue, or cell. This objective may be achieved by coupling or introducing peptides or proteins, which are able to interact with organ-specific, tissue-specific, and/or cell-specific receptor molecules into the virus using recombinant technology. Recombinant manipulation of the parapoxvirus ovis is described in the art, and this manipulation of the parapoxvirus ovis does not alter its therapeutic properties (*see, e.g.*, Robinson, et al., In: Recombinant Poxviruses, Chapter 9, 306-317 eds. M. Binns and G. Smith CRC Press, Boca Raton). Thus, the recombinant modifications described in the present invention would also not be expected to alter the therapeutic properties of the parapoxvirus ovis. Therefore, the recombinant parapoxvirus ovis as described and claimed in the present invention would be effective as a therapeutic.

It is thus submitted that the claims 1 and 2 meet the requirements of 35 USC § 112, first paragraph, and reconsideration and withdrawal of the present rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102

The Examiner rejected claim 2 under 35 U.S.C. § 102(b) as being anticipated by Robinson, et al. (WO 97/37031) (Paper No. 32104, page 6). Applicants respectfully traverse this rejection.

In order to support anticipation under 35 U.S.C. §102, each and every element of a claimed invention must be disclosed within a single prior art reference. *See In re Bond*, 15 USPQ2d 1896 (Fed. Cir. 1991).

As amended, the claims recite a method of treating or preventing a disease by administering a recombinant parapoxvirus possessing organ-specific, tissue-specific, or cell-specific targeting properties,

and a pharmaceutical composition comprising a recombinant parapoxvirus possessing organ-specific, tissue-specific, or cell-specific targeting properties.

Robinson, et al., discloses parapoxvirus vectors; however, Robinson, et al., does not teach or disclose a recombinant parapoxvirus possessing organ-specific, tissue-specific, or cell-specific targeting properties. Therefore, Robinson, et al., does not anticipate the claimed invention.

Since Robinson, et al., does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Foley is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

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Amendment to the Specifiation (Attorney Docket No. LeA 33 771)

1) Please amend the specification by inserting this paragraph on page 1 of the specification following the title:

This application is a 371 of PCT/EP00/04011, filed May 4, 2000.

2) Please amend the specification by inserting this phrase on page 1, line 5 of the specification:

Background of the Invention

3) Please amend the specification by inserting this paragraph on page 3, line 27 of the specification:

Description of the Drawings

Fig. 1 illustrates the results of a penetration assay. Bovine kidney cells were incubated with BHV-1, gDPPVO, or wt PPVO. At various times, the cells were washed with a citrate buffer thereby inactivating the viruses. Subsequently, the cells were fixed and stained, and the plaque number determined.

4) Please amend the specification by inserting this phrase on page 3, line 27 of the specification, following the amended text described above 3) Description of the Drawings:

Description of the Invention

Amended Claims (Attorney Docket No. LeA 33 771)

1. (Currently amended) A method of treating or preventing a disease comprising administering to a host in need thereof an effective amount of a recombinant parapoxvirus possessing organ-specific, tissue-specific, or cell-specific targeting properties.

2. (Currently amended) A pharmaceutical composition comprising an effective amount of a recombinant parapoxvirus possessing organ-specific, tissue-specific, or cell-specific targeting properties.